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SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Endoscopic Accessory

Proprietary Name: Hydrotower® Fluid Management System

Classification: Class II

Materials:

All materials used to manufacture the Northgate Technologies Inc. Hydrotower® Fluid Management System and tubing sets are non-toxic and have been previously used to manufacture other medical devices.

Description:

The Hydrotower® Fluid Management System incorporates a peristaltic pump, motor, controller, power supply, and associated tubing and a sensor. The product allows continuous flow to an Endoscopic instrument by the constant re-filling of a fluid "reservoir" bag. **The control of flow rates and source pressures remains in the physician's control by the conventional method of raising or lowering the "reservoir" bag.**

Substantial Equivalence:

Northgate's Hydrotower® Fluid Management System and tubing sets are substantially equivalent in design materials, and intended use to numerous currently marketed devices. Other manufactures of similar devices are Biomedical Dynamics, Olympus, Solos. Zimmer, Sun Medical, and Storz.

Intended Use:

The Nortech Hydrotower® Fluid Management System shall be used for supplying fluid for general endoscopic procedures.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Casey Kurek
Regulatory Manager
Northgate Technologies, Inc.
600 Church Road
Elgin, IL 60123

Re: K993778
Hydrotower ® Fluid Management System
Dated: December 6, 1999
Received: December 9, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Mr. Kurek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993778

Device Name: Hydrotower® Fluid Management System

Indications For Use:

THE NORTECH HYDROTOWER® FLUID MANAGEMENT SYSTEMS SHALL BE USED FOR SUPPLYING FLUID FOR GENERAL ENDOSCOPIC PROCEDURES.


C. Kurek, Regulatory Manager


(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993778